

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

Track Three Cases:

The County of Trumbull v. Purdue Pharma, et al., Case No. 18-op-45079,

The County of Lake v. Purdue Pharma, et al., Case No. 18-op-45032

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**PLAINTIFFS' RESPONSE TO THE
COURT'S REQUEST FOR INPUT
REGARDING STATUTES AND
REGULATIONS TO BE QUOTED IN
JURY INSTRUCTIONS**

CT3 Plaintiffs submit this response to the Court's request in an email from Special Master Cohen that the parties "simply identify which 'statutes, ordinances, or regulations' you believe should be *quoted* in the jury instructions." (Emphasis added.) Below, we identify those provisions that Plaintiffs think could appropriately be quoted in the jury instructions if the Court believes that direct quotation would be helpful, as well as a couple of provisions Plaintiffs do not think should be quoted to the jury.

Before turning to that subject, however, Plaintiffs believe that it is important to clarify our position: Plaintiffs do *not* think that it is necessary to quote directly from such legal provisions in the jury instructions and indeed think that it might be inadvisable to do so. (See Doc. 3449 at 85-86 ("Although [the Court] might wish to add the language of [the controlled substances laws and regulations . . . at issue], it is not necessary to do so, and it would be inappropriate not to focus on the plain language.")) The meaning of

statutes and regulations is a question of law for the Court, not a question to be decided by the jury. And many statutory and regulatory provisions contain technical language and redundancies that may cause more confusion than clarity for the jurors. The goal of any discussion of legal requirements in jury instructions must be, as the Ohio courts have opined, “to prevent the jury from being misled or confused about how to apply the statute to the evidence presented in the case.” *Smith v. Justarr, Inc.*, 102 Ohio App. 3d 506, 512, 657 N.E.2d 542, 545 (1995); *see also, e.g., Mccraney v. Mccree*, 9879, 1981 WL 3983, at *3 (Ohio Ct. App. May 20, 1981) (court could not “simply read the statute without explaining it” where terms used had “legal meanings” in the statute that did not coincide with their “more common usage”). Similarly, under federal standards, “[t]he goal of jury instructions is to aid the jury in its understanding of the applicable law, which includes both the language of the relevant statute and the case law which explains it.” *United States v. Georgiou*, 742 F. Supp. 2d 613, 634 (E.D. Pa. 2010) (instructions properly applied case-law that defined statutory terms at issue); *compare Williams v. Powers*, 135 F.2d 153, 157 (6th Cir. 1943) (“In charging a jury, the employment of the language of a statute is insufficient” where it will not “make its meaning clear and applicable to the facts”). “Overall, the relevant principle for jury instructions is not one of abstract correctness, but is whether an instruction – even if a correct statement of the law – is potentially misleading.” *State v. Rac*, 2019-Ohio-893, ¶ 18, 124 N.E.3d 878, 887 (internal quotation marks and alteration omitted).

We therefore think that the preferred approach would be for the Court simply to instruct the jury in plain language as to what the law requires or prohibits. (This could be

supplemented with the relevant statutory and regulatory citations if the Court considers that helpful.)

Plaintiffs' Recommended Approach

Thus, Plaintiffs would prefer to see the Court simply advise the jury in plain language about what the law requires along the following lines:

Opioids are controlled substances within the meaning of federal and Ohio laws and regulations.

It is unlawful for any person knowingly to distribute or dispense controlled substances other than in accordance with the requirements of the federal Controlled Substances Act ("CSA") and its implementing regulations, or in violation of the Ohio controlled substances laws and regulations.¹

It is unlawful to distribute or dispense controlled substances without providing effective controls and procedures to guard against theft and diversion under both the CSA and Ohio controlled substances laws.² The obligation to provide effective controls against diversion applies to every registrant under the CSA and Ohio law.

Under the federal and Ohio controlled substances laws, wholesale distributors, including the Defendants, have a legal duty: (1) to design and operate a system to identify suspicious orders; (2) to inform the DEA and Ohio Board of Pharmacy of suspicious orders when discovered; and (3) not to ship those orders unless investigation first shows them to be legitimate.³

Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.⁴

¹ 1 U.S.C. § 841(a); Ohio Rev. Code Ann. § 2925.03.

² 21 C.F.R. § 1301.71(a); Ohio Admin. Code 4729-9-05; Ohio Admin. Code 4729-9-16(L); Ohio Admin. Code 4729-9-28(I).

³ Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, *In re: National Prescription Opiate Litig.*, 2019 WL 3917575, at *7 & 9 (N.D. Ohio Aug. 19, 2019); Ohio Admin. Code 4729-9-16(H)(1)(e); Ohio Admin. Code 4729-9-28(E).

⁴ 21 C.F.R. § 1301.74(b).

In retail pharmacy stores, it is unlawful to dispense a controlled substance without a valid prescription.⁵ A prescription, to be effective, must be issued for a legitimate medical purpose in the usual course of a professional practice.⁶ An order purporting to be a prescription that does not meet this definition is not a “prescription” within the meaning of state and federal controlled substances laws, and it is a violation of those laws to knowingly fill such a purported prescription.⁷ A pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind to the prescription information it has, including computerized reports it maintains. Employment of a pharmacist does not relieve a pharmacy or pharmacy owner of the obligation to ensure that only valid prescriptions are filled.⁸

Pharmacies must “maintain systems, policies, or procedures to identify prescriptions that bear indicia (‘red flags’) that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use.”⁹ “Dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances.”¹⁰ Pharmacies also have an obligation under Ohio law to maintain adequate safeguards in their business to “allow[] pharmacists ... to practice pharmacy in a safe and effective manner.”¹¹

⁵ 21 U.S.C.A. § 829.

⁶ 21 C.F.R. § 1306.04.

⁷ *Id.*

⁸ Opinion and Order denying Defendants’ motion to dismiss, Dkt. 3403 at 13-25; *see also Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at *24 (Ohio Ct. App. 11th Dist. May 8, 2001) (explaining that the Ohio Administrative Code “places the ultimate responsibility upon the ‘registrant’ ... to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs” and that “licensees electing to operate a business through employees are responsible to the licensing authority for their conduct”).

⁹ Dkt. 3403 at 21-22 & 24-25.

¹⁰ *Id.* at 24-25; O.R.C. § 4729.55(D).

¹¹ *Id.* at 20 & 24; O.R.C. § 4729.55(D).

Statutory Citations

If the Court is nevertheless inclined to include direct quotations from statutes and regulations in the jury instructions, Plaintiffs would suggest that it would be appropriate to consider including the following passages:

Opioids are controlled substances within the meaning of federal and Ohio laws and regulations.

“Except as authorized by [the federal Controlled Substances Act (“CSA”)], it shall be unlawful for any person knowingly or intentionally to . . . distribute or dispense, or possess with intent to . . . distribute or dispense, a controlled substance.” **21 U.S.C. § 841(a).**

All registrants under the CSA must “provide effective controls and procedures to guard against diversion,” and it is a violation of the CSA for any registrant to distribute or dispense a controlled substance without providing such controls. **21 C.F.R. § 1301.71(a).**

Under the CSA, a distributor “shall design and operate a system to disclose to [it] suspicious orders of controlled substances.” **21 C.F.R. § 1301.74(b).**

Implicit in this requirement is an obligation to use that system to halt suspicious orders unless and until due diligence disproves the suspicion. *Id.*

Only DEA registrants may distribute or dispense controlled substances. A DEA registrant “shall inform the Field Division Office of the [DEA] in his area of suspicious orders when discovered by the registrant.” **21 C.F.R. § 1301.74(b).**

“Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” **21 C.F.R. § 1301.74(b).**

The CSA also prohibits dispensing controlled substances without a prescription. **21 U.S.C.A. § 829.**

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” **21 C.F.R. § 1306.04.** “An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)” and “knowingly filling such a purported prescription” violates the CSA. *Id.*

Under Ohio law, no person shall “[s]ell or offer to sell a controlled substance” except as authorized by the Ohio controlled substances statutes and regulations. **Ohio Rev. Code Ann. § 2925.03.** These regulations incorporate the federal requirements described above. Specifically, “[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.” **Ohio Admin. Code 4729-9-16(L); Ohio Admin. Code 4729-9-28(I).**

Under Ohio law, distributors and pharmacies must obtain a state license, or registration, in addition to the federal registration. “All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs.” **Ohio Admin. Code 4729-9-05.**¹²

For wholesalers, “[a] system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse. The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler’s records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.” **Ohio Admin. Code 4729-9-16(H)(1)(e).**

“A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. . . . An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.” **Ohio Admin. Code 4729-5-21(A).**

“No license shall be issued to an applicant for licensure as a terminal distributor of dangerous drugs [which includes a pharmacy] unless the applicant has furnished satisfactory proof to the state board of pharmacy that: . . . [a]dequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.” **O.R.C. § 4729.55(D).**

¹² This submission uses the regulations in force at the time these actions were originally filed. As the Court recognized in its Opinion and Order denying Defendants’ motion to dismiss, “Sections 4729-9-05(A) and 4729-9-16(H) of the Code were recently rescinded, revised, and reorganized” and provisions cited therein “now appear at §§ 4729:5-3-14 and 4729:6-3-05.” Dkt. 3403 at 5 n.8.

Provisions that Should Not Be Included in Jury Instructions

Finally, Plaintiffs wish to identify two passages from regulations referenced in Special Master Cohen's email that we do not believe should appropriately be included in jury instructions, because they are not relevant to any issue to be decided by the jury and are likely to lead to juror confusion. Specifically, Plaintiffs do not believe that either of the following passages should be included in the instructions:

21 C.F.R. § 1301.71(a): "In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion."

21 C.F.R. § 1301.71(b): "Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant."

As to the first of these passages, the Court has already decided what the Defendants' obligations are. The language quoted above does not set forth any obligations of registrants. Rather, it relates to how the DEA determines whether a registrant has provided effective controls. If a referenced section is relevant to the determination to be made by the jury in this case — that is, if it provides a standard with which Defendants must comply — it should be quoted (thus, the inclusion of § 1301.74 with respect to distribution claims). If a referenced section is *not* applicable here, there is no reason to quote it, and its inclusion in jury instructions threatens to confuse the jury. The inference that Defendants argued could be drawn from this portion of the regulation — that compliance with the physical security requirements is *all* that is required

to provide effective controls against diversion—is a legal question of statutory/regulatory interpretation for the Court. Quotation of this passage is especially inappropriate because the Court has already rejected the inference/significance that Defendants argued attached to this language.

As to the latter passage concerning “substantial compliance” with the security requirements, Plaintiffs would object to this being quoted because the fact that the DEA is empowered to overlook insubstantial violations of law does not mean the law has not been violated; it goes only to the regulatory consequences of those violations. As the DEA’s Rule 30(b)(6) designee testified in this litigation, shipping a suspicious order is a *per se* violation of federal law. Prevoznik Dep. Vol II, 632:7 to 633:2, April 18, 2019 (DEA 30(b)(6) designee).

Plaintiffs would be happy to further address any of the foregoing points and concerns with the Court upon request.

Respectfully submitted,

/s/Paul J. Hanly, Jr.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 6th day of November, 2020, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF System.

/s/Peter H. Weinberger

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